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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,913	10/20/2003	Rudolf Wank	1033285-000019	2270

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EXAMINER	
SKELDING, ZACHARY S	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/687,913	WANK, RUDOLF	
	Examiner	Art Unit	
	Zachary Skelding	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *14-39* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's Election, with traverse, filed August 18, 2006, is acknowledged.

Claims 1-13 have been canceled.

Claims 14-39 have been added.

Claims 14-39 are pending.

2. Applicant has provisionally elected, with traverse, the following species:

For the first step of the stimulation process, i.e., "producing activated antigen presenting cells (APC) by…exposure peripheral-blood mononuclear cells (PBMC)… obtained from a first biopsy" (claim 1, step (a)), applicant elects "anti-CD3 antibody" as the agent.

For the second step of the stimulation process, i.e., "incubating the naïve PBMC in the presence of the activated PBMC" (claim 1, step (c)), applicant elects "IL-2" as the agent.

Applicant further elects method where the CAPRI cells are administered to a patient and that the method of treating a patient further comprises radiotherapy.

3. Applicant has traversed the Election of Species requirement on the grounds that the prior Restriction Requirement fails to provide a basis that the species are independent and/or distinct and that fails to explain why the searching the species would be burdensome.

Applicant's argument is not found persuasive essentially for the reasons of record.

Therefore, the Election of Species requirement is maintained and made **FINAL**.

Nevertheless, applicant has canceled all of the previous claims and presented new claims.

Applicant's amendment to the claims has necessitated a recasting of the Groups of the previous Restriction Requirement.

Accordingly, the previous Restriction Requirement is hereby **VACATED**. The following new Restriction Requirement is set forth. The Examiner apologizes for any inconvenience to applicant in this matter.

5. It is noted that new claims 29-39 are drawn to a method of ***treating cancer*** using "**the CAPRI cells of claim 14**".

   However, claim 14 is ***not*** drawn to CAPRI cells ***per se***, rather, it is drawn to a **method of making** CAPRI cells.

   Accordingly, for the purposes of examination, claims 29-39 will be restricted to the extent they read on a ***method of treating cancer*** using the CAPRI cells ***made by the method*** recited in claim 14.

Restriction Requirement

6. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

   I. Claims 14-28, drawn to an ***in vitro method of making*** CAPRI cells having specificity for cancer antigens, classified in Class 435, subclass 373.

   II. Claims 29-39 drawn to an ***in vivo method of treating cancer*** with CAPRI cells, classified in Class 424, subclass 93.71.

   Groups I and II are different methods, which differ with respect to one or more ingredients, method steps, and ***endpoints***; therefore, each method is patentably distinct. Further, the distinct ingredients, method steps, and ***endpoints*** require separate and distinct searches. Furthermore, they require non-coextensive searches in the scientific literature. As such, it would be burdensome to search these inventions together.

   Moreover, while CAPRI cells, *per se*, made by the method of Group I have **not** been claimed, assuming *arguendo* that they were, the instant claims would be analogous to product, a process of making that product, and a process of using that product claim set. If this were the case, the product, process of making the product, and process of using the product would be restricted into separate groups since cancer can be treated with a materially different product, such as a chemotherapeutic agent, and "CAPRI cells" can be made by a materially different process, for example, by producing the activated antigen presenting cells of the first step of claim 14 not as claimed by rather by transfecting tumour cells obtained from a first biopsy (see for example, instant specification page 2, 2nd paragraph, with genes that activate T cells, such as an expression construct that produces a membrane bound anti-CD3 antibody.

Species Election

7. This application contain claims directed to the following patentably distinct species of the claimed invention:

8. **If applicant elects Group I**, Applicant is required to elect a specific **agent or a single combination of agents that activate T-cells** that will be used in the first step of the in vitro method for making CAPRI cells, from, for example the following species disclosed on page 5, 1st and 2nd paragraphs of the instant specification and in claims 22, 25 and 26:

a. anti-CD3 antibody,
b. immobilized CD3,
c. IL-2,
d. IL-4,
e. IFN-γ.
f. GMCSF,
g. anti-B7 antibody,
h. a lectin; **OR**
i. a calcium ionophore.

AND

Applicant is **further required to elect specific agent or a single combination of agents selected from, for example, a.-i. above, which will be present *after* the addition of naïve PBMC to the cells stimulated in the first step,** i.e., ***in the third step*** of the in vitro method for making CAPRI cells.

These agents are patentably distinct because they differ in their structures, and/or physiochemical properties, and do not share a common structure that is disclosed to be essential for common utility. Further, examination of these species would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

If applicant believes these species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case.

Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

9. **If applicant elects Group I, applicant is further required** to elect the particular sources of PBMCs for the method steps employing PBMC obtained from a first biopsy and PBMC obtained from a second biopsy from among the following:

(A) both PBMC are obtained from a single donor, for example, as in claim 16, **OR**

(B) the PBMC used in the **first step** are obtained from a cancer patient and the PBMC used in the second step are from a donor that expreses a **"HLA haplotype of sufficient similarity to the HLA haplotype of the cancer patient",** for example, as in claims 17 and 19, **OR**

(C) the PBMC used in the **second step** are obtained from a cancer patient and the PBMC used in the first step are from a donor that expreses a **"HLA haplotype of sufficient similarity to the HLA haplotype of the cancer patient",** for example, as in claim 18, **OR**

(D) both PBMC are obtained from a single donor wherein said donor expreses a **"HLA haplotype of sufficient similarity to the HLA haplotype of a cancer patient"**, for example as in claim 20.

Methods employing these different cells and/or steps are patentably distinct because these methods differ with respect to one or more method steps and/or endpoints. **For example, species (B), (C) and (D) differ from (A)** because determining if two PBMC populations have "sufficiently similar HLA haplotypes" entails first determining which particular "HLA haplotype" is expressed by the target cancer cell of interest and then finding a donor who has PBMC cells that have a "sufficiently similar HLA haplotype" ***before*** the first step of the method can be carried out. **Moreover, species (B) and (C) differ** in that the method of species (C) requires not only that one determine if the PBMC cell populations to be mixed have HLA haplotypes of sufficient similarity, but also if the PBMC of the first step will present an antigen, e.g., an HPV antigen as disclosed on page 7, bullet 2, that one would want to use to prime the PBMC of the second step for their intended use, e.g., to create T-cells that target HPV infected cells. **Lastly, species (D) differs from (B) and (C)** in that while the particular PBMCs used is determined by the requirement that the PBMCs expreses a **"HLA haplotype of sufficient similarity to the HLA haplotype of a cancer patient"**, once the requisite PBMCs are obtained the method is more predictable because the PBMCs to be mixed are of the same haplotype rather than a "sufficiently similar haplotype" which could encompass a wide variety of the exceptionally polymorphic and polygenic HLA loci, dependent upon what is meant by "sufficiently similar haplotype".

Furthermore, the examination of the different method steps and/or endpoints would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

If applicant believes these species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case.

Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

AND

If (D) from the previous page is selected, applicant is **further required** to elect if:

(A) the allogenic donor is **not** exposed to an **"identifiable carcinogenic factor"**, **OR**

(B) the allogenic donor is exposed to an **"identifiable carcinogenic factor",** for example, as described in the paragraph briding pages 11-12.

The methods employing these allogenic donor exposed or not exposed to an **"identifiable carcinogenic factor"** are patentably distinct because they differ with respect to one or more of ingredients, method steps and/or endpoints. Furthermore, the examination of the different ingredients, method steps and/or endpoints would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

If applicant believes these species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case.

Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

AND

If **(B)** is selected, applicant is further required to elect a specific "identifiable carcinogenic factor", for example, from the "identifiable carcinogenic factors" disclosed in the paragraph briding pages 11-12, such as "HPV 16/18" **OR** "JC virus".

These "identifiable carcinogenic factors" are patentably distinct because they differ in their structures, and/or physiochemical properties, and do not share a common structure that is disclosed to be essential for common utility. Further, examination of these species would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

If applicant believes these species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case.

Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

10. **If applicant elects Group II, applicant is required** to elect one specific **"cancer to be treated"**, for example, from among those recited in claims 30, such as **"melanoma" OR "breast carcinoma" OR "bowenoid papilloma"**.

These pathological conditions are patentably distinct because they differ in etiologies and therapeutic endpoints. Furthermore, the examination of species would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

If applicant believes these species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case.

Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

11. **If applicant elects Group II, applicant is further required** to elect if:

(A) the administered CAPRI cells does **not** further comprise administration of CD-3 activated T-cells to a patient, **OR**

(B) the administered CAPRI cells does further comprise administration of CD-3 activated T-cells to a patient, as in, for example, claim 35.

These methods are patentably distinct because they differ with respect to one or more method steps and/or endpoints. Furthermore, the examination of the different method steps and/or endpoints would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

If applicant believes these species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case.

Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

12. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, **and a listing of all claims readable thereon**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

13. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary Skelding whose telephone number is 571-272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Zachary Skelding, Ph.D.
Patent Examiner
November 13, 2006

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11/13/06